

REMARKS

Claims 97-133 are pending in the application, of which claims 97, 98, 100, 101, 103-114, and 116-133 have been withdrawn by the Examiner and are cancelled without prejudice. Applicants thank the Examiner for renumbering the claims, and Applicants have accordingly amended the numbering of the claims. Claims 99, 102 and 115 have been amended. No new matter has been added by such amendment. Amendment of the pending claims and specification should in no way be construed as an acquiescence, narrowing, or surrender of any subject matter. Rather, the amendments are being made to expedite prosecution of the present application. Applicants reserve the option to prosecute the previously pending claims further, or other ones, in the instant or a subsequent patent application.

Applicants have amended claims 99, 102, and 115 to recite that the components of the claimed composition synergistically reduce HbA1c levels. Support for the claim amendments

- may be found throughout the specification, including the claims as originally filed. Further, Applicants submit with this Response as Exhibit A hereto a PCT publication, WO 00/57729, which shows that use of embodiments of the present invention achieves the synergistic reduction of HbA1c levels, as now claimed in all of the pending claims. This PCT application is assigned to the assignee of this Application, Akesis Pharmaceuticals. Tables 101-118 on pages 69-90 of such publication set forth clinical data resulting from the administration of those embodiments to approximately 81 patients.

In such publication, Tables 109 and 110 show the synergistic results achieved by using one embodiment of the claimed composition. In Table 109, the middle box shows that eight patients had an average HbA1c level of 10.3% before treatment with this embodiment while on metformin alone. Table 110 shows a reduction in HbA1c levels after treatment with this embodiment, which reduction is referred to in the claims as “synergistic”. Referring to the middle box in Table 110, for example, the HbA1c levels for the same eight patients dropped to 8.2% after treatment, *an absolute drop of over 2.1%*. This decrease occurred after treatment of metformin as part of this embodiment as compared to treatment with metformin alone. The Tables show similar synergistic results for many of other anti-diabetic agents in various embodiments of the present invention.

CLAIM REJECTIONS

Rejection of claims under 35 U.S.C. § 102(a)

The Examiner has rejected claims 99, 102, 103, 115, and 116 as anticipated under 35 U.S.C. § 102(a) by Gutierrez, et al. (U.S. 5, 885,980). Applicants respectfully submit that the amendments to the claims render the rejection moot. A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. (Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).) All of the pending claims require a “bioavailable source of chromium”. Gutierrez, et al. does not disclose a composition containing chromium, and thus does not teach each and every element of the claims in the present application. Therefore, reconsideration and withdrawal of the rejection of claims under 35 U.S.C. 102(a) is respectfully requested.

Double-Patenting

Applicants will submit a terminal disclaimer in accordance with 37 C.F.R. § 1.321(c). to disclaim the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of Issued U.S. Patent No. 6,376,549.

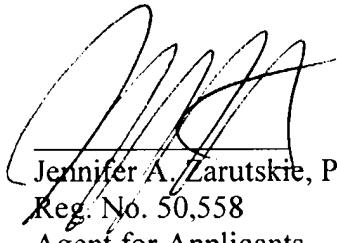
CONCLUSION

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims now pending are in condition for allowance, and notification of such is respectfully requested.

The Commissioner is hereby authorized to credit any overpayment or charge any deficiencies to Deposit Account Number **06-1448, Reference AKT-053.02**.

If, for any reason, a telephonic conference with the Applicant would be helpful in expediting prosecution of the instant application, the Examiner is invited to call Applicants' Agent at the telephone number provided below.

Respectfully submitted,
FOLEY HOAG



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